NOT FOR PUBLICATION [94]

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

RECKITT BENCKISER INC. and UCB MANUFACTURING, INC.	:	
	:	
Plaintiffs,	:	Civil Action No. 09-3125 (FLW)
v.	:	**OPINION**
	:	
TRIS PHARMA, INC. and YU-HSING TU,	:	
Defendants.	:	

WOLFSON, United States District Judge:

Presently before the Court is a Motion for Summary Judgment of Non-infringement by Defendants Tris Pharma Inc. ("Tris") and Yu-Hsing Tu ("Dr. Tu")(collectively "Defendants"). The instant motion arises out of a Complaint filed by Plaintiffs Reckitt Benckiser Inc. ("Reckitt") and UCB Manufacturing, Inc. ("UCB") (collectively "Plaintiffs") alleging, inter alia, infringement of U.S. Patent No. 5,980,882 ("the '882 patent") by Defendants' submission of an Abbreviated New Drug Application ("ANDA") to market a generic version of the over-the-counter cough syrup Delsym, which is made by Reckitt and allegedly covered by the '882 patent owned by UCB. In this motion, Defendants allege that Plaintiffs have not demonstrated that Defendants' use of EDTA results in the claimed 20 percent reduction in degradation over twelve months of a pharmaceutical composition with EDTA versus an otherwise identical

pharmaceutical composition without EDTA, as required by Claims 23, 26 and 36 of the '882 patent (the "asserted claims").[1] As a result, Defendants allege that Plaintiffs cannot establish infringement and, therefore, that summary judgment is warranted. The Court agrees and for the reasons set forth below, grants Defendants' motion for summary judgment.

I. BACKGROUND

Because the facts of this case are well known to the parties, and in light of the three Opinions already issued by this Court in this matter, the Court will only recite the relevant facts herein and will, instead, incorporate the facts recited in the previous Opinions issued by this Court.

The '882 patent, entitled "Drug-Resin Complexes Stabilized by Chelating Agents," claims certain pharmaceutical compositions using a drug-resin complex and a chelating agent and certain methods of making these pharmaceutical compositions. The claims of the '882 patent include Delsym and its method of production. The active ingredient in Delsym is dextromethorphan, a common cough suppressant that has been on the market for at least 50 years. Delsym contains dextromethorphan in an extended release form so it can be taken less frequently than a conventional cough syrup. When swallowed, the dextromethorphan is released over a period of time. The '882 patent, the patent at issue here, claims an "improved" formulation of Delsym to which an extra ingredient – the common preservative or stabilizer called edtate disodium ("EDTA" or "a salt of EDTA") has been added.

Importantly, and in relevant part, Claim 23 of the '882 patent recites "[a] method for

[1]Indeed, the Court notes that in a letter dated November 4, 2011, counsel for Plaintiffs voluntarily dismissed claims 24 and 25 of the '882 patent.

improving the stability of a pharmaceutical composition that contains a drug-resin complex comprising adding a chelating agent in an amount effective to reduce the rate of degradation of the drug in the drug-resin complex by more than 20 percent over twelve months of storage at room temperature relative to an otherwise identical pharmaceutical composition without the chelating agent." Thus, to prove infringement, Plaintiffs must establish that the accused product (which contains EDTA) reduces the rate of degradation by more than 20 percent over twelve months of storage as compared to an otherwise identical product without EDTA. Claims 26 and 36, the remaining claims asserted in this matter, are dependent upon Claim 23.[2]

In November 2010, this Court issued an Opinion construing various claims of the '882 patent. Subsequently, in February 2011, this Court issued an Opinion dismissing a Breach of Contract count from the amended complaint. Thereafter, in May 2011, the parties met and conferred regarding certain outstanding discovery issues. As a result, the parties agreed to the following schedule: the completion of document production on June 10, 2011; the close of fact discovery on July 8, 2011; that opening expert reports would be due on July 27, 2011; that rebuttal expert reports would be due on August 24, 2011; and that expert discovery would close on September 16, 2011. The Magistrate Judge "SO ORDERED" the agreed-upon schedule on June 3, 2011.

In accordance with the schedule, on July 27, 2011, Plaintiffs timely served the opening expert report of Dr. Stephen R. Byrn ("Opening Report"). Indeed, in relevant part, in the Opening

[2]Claim 26 recites, "[a] method according to claim 23, wherein the composition is a suspension." Similarly, Claim 36 recites, "A method according to claim 23, wherein the drug in the drug-resin complex is dextromethorphan."

Report, Dr. Byrn made the following reference to an independent laboratory's manufacture of Tris's product:

> I understand that Counsel for Reckitt Benckiser and UCB requested an independent laboratory to manufacture Tris's Proposed ANDA product with and without the EDTA-washed resin and conduct stability testing at room temperature over twelve months. The data available after nine months establishes that the EDTA-washed resin in Tris's proposed ANDA product reduces the rate of degradation by 57.3% over nine months and meets this part of the claim limitation. Following normal linear degradation, a similar reduction in degradation would occur after twelve months. I summarize the available data below. I reserve the right to supplement this report as additional data becomes available.

Opening Report ¶ 67.

On August 24, 2011, Plaintiffs timely served Dr. Byrn's rebuttal expert report ("Rebuttal Report"). Thereafter, on August 26, 2011, Defendants filed the instant motion for summary judgment based, in part, on the opening and rebuttal reports of Dr. Stephen R. Byrn. In their opening brief, Defendants argued that summary judgment was warranted because Plaintiffs failed to meet the requirements of Claim 23 since they did not demonstrate that the accused product (which contains EDTA) reduces the rate of degradation by more than 20 percent over twelve months of storage as compared to an otherwise identical product without EDTA. Specifically, Defendants contend that Plaintiffs could not establish infringement by merely: (1) comparing the stability of the accused product to the stability of Plaintiffs' product, Delsym; (2) pointing to the stability of an experimental Tris product; or (3) relying on a statement by Dr. Byrn concerning an independent laboratory's "manufacture of Tris's Proposed ANDA product with and without the EDTA-washed resin" over a nine month period that was wholly unsupported by any reasonable basis.

On September 13, 2011, after receiving Defendants' summary judgment motion, but prior to filing any Opposition thereto, and without seeking permission of the Court, Plaintiffs served a supplemental expert report of Dr. Byrn ("Supplemental Report"). Importantly, and in relevant part, the Supplemental Report analyzed, for the first time, the independent laboratory tests conducted between August 2010 and September 2011 of the samples manufactured by Plaintiffs that allegedly replicate Defendants' accused product.

Thereafter, on September 21, 2011, Plaintiffs filed a Brief in Opposition to Defendants' summary judgment motion. Specifically, Plaintiffs argue that they have multiple sets of data showing that Defendants' product infringes the Improved Stability Limitation set forth in Claim 23 and that such data are sufficient to defeat the instant motion for summary judgment. In support of their Opposition, Plaintiffs attached the Supplemental Report of Dr. Byrn and, additionally, included a declaration from Dr. Byrn containing information from the Supplemental Report.

As a result, on September 21, 2011, Defendants immediately filed an informal motion to strike the Supplemental Report. In the motion, Defendants alleged that they were unduly prejudiced by the late and unauthorized submission of the Supplemental Report, which contained substantial new data and information that went well beyond the scope of Dr. Byrn's opening report. Specifically, Defendants argued that "the new report is the first time that Dr. Byrn expresses any opinion on the manufacturing and testing methods used by Aptuit, despite the fact that this information was available in August 2010, almost a full year before opening expert reports were due. . . .This is also the first time that Dr. Byrn renders opinions on the reliability of Aptuit's alleged results, including statistical analysis and kinetic modeling." Defs' Mot. to Strike

(Sept. 21, 2011)("Def's Sept. 21 Letter") at 3. Moreover, Defendants contended that they were additionally prejudiced by "[P]laintiffs' concealment that samples were being manufactured and tested by Aptuit throughout fact discovery. Underlying data from third party laboratories. . .were requested by [D]efendants yet never produced." Id.

Dr. Byrn was deposed on October 3, 2011. During his deposition, Dr. Byrn appears to admit that he did not analyze the data about which he opined in paragraph 67 of his Opening Report, and, moreover, that his only understanding that the third party data replicated Defendants' products and method was based on what Plaintiffs' attorneys told him. Defs' Reply in Support of Motion to Strike (Oct. 7, 2011)("Defs' Oct. 7 Letter.")[3]

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[3]In support of their assertion, Defendants cite to the following deposition testimony:

Q. Now, when you say you understand that counsel for Reckitt Benckiser UCB requested the independent laboratory and you put the data here in paragraph 67, what other information did you have at the time about how the tests were done?
A. The understanding I had was that they had repeated the process, the Tris process, using the Tris batch records and the Tris contents and the procedure that Tris had used.
Q. And what understanding was that based – on what was that understanding based?
A. What I was told.
Q. By whom?
A. By the attorneys.

* * *

Q. At the time you prepared this expert report, you did not know that the work that was told to you by the attorneys for plaintiffs had been done by Aptuit; true?
A. I don't think I knew that.
Q. You had not audited the Aptuit methods; correct?
A. I understood that it was a replication of the Tris method.
Q. Because that's what the lawyers told you; correct?
A. Correct.
Q. You didn't independently verify that?
A. Correct.

Defs' Oct. 7, Letter, at 2-3.

On October 21, 2011, the Magistrate Judge held oral argument on Defendants Motion to Strike the Supplemental Report and, on that same date, issued an Order striking the Supplemental Report. Plaintiffs appealed the Magistrate Judge's October 21, 2011 Order. In an opinion dated, December 21, 2011, I affirmed the Magistrate's Order in its entirety. As a result, this Court will not consider the Supplemental Report, nor any information contained within Dr. Byrn's declaration that stems from the Supplemental Report, in deciding the instant motion for summary judgment.

II. LEGAL STANDARD

Summary judgment serves to "isolate and dispose of factually unsupported claims." Celtex Corp. v. Catrett, 477 U.S. 317, 323-24 (1986). It "shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as matter of law." Fed. R. Civ. P. 56(c); see Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248-50 (1986). Summary judgment is just as appropriate in a patent case as in any other civil case. Paragon Podiatry Lab. v. KLM Labs., Inc., 984 F.2d 1182, 1190 (Fed.Cir.1993). In addition, in deciding a motion for summary judgment, "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986).

The patentee must prove infringement by a preponderance of the evidence. Mannesmann Demag Corp. v. Enginerred Metal Prods. Co. Inc., 793 F.2d 1279, 1282 (Fed. Cir.1986). To prove infringement of a patent claim to a method, the patentee must prove that every step in the

method is performed by the accused process, either literally or under the doctrine of equivalents. Canton Bio-Medical, Inc. v. Integrated Liner Techs., Inc., 216 F.3d 1367, 1370 (Fed. Cir.2000). The absence of any one limitation of a claim in the accused process precludes a finding of literal infringement of that claim. Kahn v. GMC, 135 F.3d 1472, 1477 (Fed. Cir.1998). Summary judgment of non-infringement is, therefore, appropriate where no reasonable jury could find that the accused process carries out each and every step of the claim or its equivalent. Goldenberg v. Cytogen, Inc., 373 F.3d 1158, 1163-64 (Fed. Cir.2004). On the other hand, summary judgment of infringement is proper when "no reasonable jury could find that any limitation in a properly construed claim is missing from an accused device." PC Connector Solutions LLC v. SmartDisk Corp., 406 F.3d 1359, 1364 (Fed. Cir.2005).

Specifically, for literal infringement, the accused product or process must "contain each limitation of the claim exactly" and there cannot be "any deviation from the claim." Litton Sys. v. Honeywell, 140 F.3d 1449, 1454 (Fed.Cir.1998); see also Telemac Cellular Corp. v. Topp Telecom, Inc., 247 F.3d 1316, 1330 (Fed.Cir.2001). If each limitation is not satisfied exactly, infringement may still be found under the doctrine of equivalents, but only if the difference between the claim limitation not present literally and the corresponding element in the accused device or process is "insubstantial." Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 39-40 (1997); Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1139, 1351 (Fed. Cir.2003). An accused device may infringe under the doctrine of equivalents only if it possesses all of the limitations of the relevant claim either literally or equivalently. See Warner-Jenkinson Co., 520 U.S. at 40-41.

Thus, a determination of infringement requires a two-step analysis. "First, the court

determines the scope and meaning of the patent claims asserted.... [Second,] the properly construed claims are compared to the allegedly infringing device." Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454 (Fed.Cir.1998) (en banc) (citations omitted). Step one, claim construction, is an issue of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed. Cir.1995) (en banc), aff'd, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Step two, comparison of the claim to the accused device, requires a determination that every claim limitation or its equivalent be found in the accused device. See Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 29 (1997). Those determinations are questions of fact, and on summary judgment, the issue is whether there is no genuine issue of material fact regarding infringement. Bai v. L & L Wings, Inc., 160 F.3d 1350, 1353 (Fed. Cir.1998). Summary judgment of noninfringement may only be granted if, after viewing the alleged facts in the light most favorable to the nonmovant and drawing all justifiable inferences in the nonmovant's favor, there is no genuine issue whether the accused device is encompassed by the patent claims. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1304(Fed. Cir.1999).

III. DISCUSSION

In the instant matter, each of the asserted claims – 23, 26 and 36 – requires a comparison over twelve months between a product with EDTA and an otherwise identical product without EDTA resulting in a greater than 20 percent reduction in degradation of the drug when EDTA is added. In this regard, Defendants argue, that because Plaintiffs have not set forth any evidence of the required comparison between the accused product and an otherwise identical product made

without EDTA over a twelve month period, summary judgment is warranted.

Defendants assert three separate bases for their motion. First, Defendants contend that Plaintiffs cannot rely on third-party test data provided by Aptuit to demonstrate infringement. Next, Defendants argue that because Plaintiffs only compared the accused Tris product to Delsym, they did not meet the specifications of Claim 23 which require a comparison of the accused product with "an otherwise identical pharmaceutical composition without" EDTA. Finally, Defendants argue that Plaintiffs compared an experimental Tris product to the Claims rather than comparing the accused Tris product to the Claims. For the reasons set forth below, the Court grants Defendants' motion for summary judgment of non-infringement.

A. Third Party Laboratory Test Data

In his Opening Report, Dr. Byrn relies on third party test data provided by Aptuit, an independent laboratory, to demonstrate that Defendants' product infringed the '882 patent. Specifically, and in relevant part, Dr. Byrn opined that:

> I understand that Counsel for Reckitt Benckiser and UCB requested an independent laboratory to manufacture Tris's Proposed ANDA product with and without the EDTA-washed resin and conduct stability testing at room temperature over twelve months. The data available after nine months establishes that the EDTA-washed resin in Tris's proposed ANDA product reduces the rate of degradation by 57.3% over nine months and meets this part of the claim limitation. Following normal linear degradation, a similar reduction in degradation would occur after twelve months.

Opening Report ¶ 67.

In the instant motion, Defendants contend that Plaintiffs cannot rely on the third-party test data provided by Aptuit to demonstrate infringement. Specifically, Defendants argue that: (1)

Plaintiffs have not shown that the Aptuit product is the same as Tris's ANDA product; and (2) Dr. Byrn's opinions are not shown to be based on reliable and scientific methods.[4] The Court agrees.

Since the burden of proving infringement rests with the patentee, an accused infringer seeking summary judgment may "meet its initial responsibility either by providing evidence that would preclude a finding of infringement, or by showing that the evidence on file fails to establish a material issue of fact essential to the patentee's case." Novartis Corp. V. Ben Venue Labs., Inc., 271 F. 3d 1043, 1046 (Fed. Cir. 2001). In the context of a summary judgment motion, the Federal Circuit has explained, "[u]nder modern summary judgment law, a patentee who fails to provide probative evidence of infringement runs the risk of being peremptorily nonsuited . . . Evidence from which a reasonable fact-finder could find infringement will forestall this possibility. However, a party does not meet this evidentiary threshold merely by submitting the affidavit of an expert who opines that the accused device meets the claim limitations." Id. at 1050-1051(citations omitted). Instead, the Federal Circuit requires "that the factual predicate of an expert's opinion must find some support in the record, and has emphasized that mere 'theoretical speculations' lacking a basis in the record will not create a genuine issue of fact. . . Moreover, where an expert's opinion is predicated on factual assumptions, those assumptions must also find some support in the record." Id. at 1051.

[4] In addition, Defendants argue that Dr. Byrn's supplemental reports are inadmissible; for the reasons set forth in the Magistrate Judge's October 21, 2011 Order striking the Supplemental Report, as well as this Court's December 21, 2011 Opinion affirming the Magistrate Judge's October 21, 2011 Order, this Court will not consider this argument nor will the Court consider the Supplemental Report.

For example, in Novartis v. Ben Venue Laboratories, Inc., 271 F. 3d 1043 (Fed. Cir. 2001), the Federal Circuit affirmed a district court's grant of summary judgment of non-infringement where the patentee failed to present sufficient evidence to raise a fact issue regarding infringement. Specifically, in an attempt to defeat the accused infringer's motion for summary judgment, the patentee introduced an expert's opinion that, based on a computer model, the accused product formed the necessary crystalline structure during the manufacturing process. However, the expert did not provide any supporting evidence to show how its model accurately approximated the accused infringer's manufacturing process. There, the Federal Circuit faulted the expert declaration for failing to explain the basis for his model, and, specifically, failing to explain what facts of record the expert based his model upon or the assumptions he employed in making the model. Indeed, the court explained that "every simulation of a physical process embodies at least some simplifying assumptions, and requires both a solid theoretical foundation and realistic input parameters to yield meaningful results. Without knowing these foundations, a court cannot evaluate whether the simulation is probative, and it would be unfair to render an expert's opinion immune to challenge because its methodology is hidden in an uncommented computer model . . . under our law and the law of the Third Circuit it was [plaintiff's] obligation to set forth detailed basis of its evidence such that the district court could evaluate whether it could support a finding of infringement by a reasonable fact-finder. Without such basis . . . we must regard [the expert's] opinion] as no more than theoretical speculation raising, at best, a 'metaphysical doubt as to the material facts.'" Id. at 1054 (citations omitted).

Conversely, in Dow Chemical Co., v. Nova Chemicals Co., Civ. A. No. 05-737, 2010 WL 2044931 (D.Del. May 20, 2010), defendants argued that summary judgment based on non-

infringement was proper because plaintiff could not establish the elements of infringement. There, defendant argued that plaintiff could not show that the accused polymer met the limitation requirements based on the method by which plaintiff tested the product. Specifically, defendant argued that "because [plaintiff] ran tests on a version of the accused product it created and did so under different polymerization conditions and with a different co-catalyst than [defendant] uses, there is no valid evidence of infringement." Id. at *4. In denying defendant's motion for summary judgment, the court explained that "the first argument presented by [defendant] was that the accused product has not been shown to have [a qualifying component] because Dow tested on fabrications of the accused product it made and not on the actual product." Id. However, the court went on to explain that plaintiff had sustained its burden to defeat summary judgment because plaintiff "has produced sufficient evidence that the testing procedures it carried out were scientifically acceptable and based on the accused product. There was testing by a qualified expert in an appropriate setting and the expert also offered substantial explanation for his actions." Id. at *5. In contrast, the facts extant before this Court fall short in these respects.

In the instant matter, the entirety of the evidence in the record before me concerning the third-party testing consists of three sentences in Dr. Byrn's Opening Report and pertains to tests that Dr. Byrn did not supervise, design or conduct.[5] Specifically, Dr. Byrn opines, in relevant part,

[5]Importantly, the Court notes that it is well-established that "an expert need not have obtained the basis for his opinion from personal perception . . . Likewise, numerous courts have held that reliance on scientific test results prepared by others may constitute the type of evidence that is reasonably relied upon by experts for purposes" of the Federal Rules. Monsanto Co. v. David, No.2007–1104, 2008 WL 304751 (Fed.Cir. Feb.5, 2008) (citing Ratliff v. Schiber Truck Co., 150 F.3d 949, 955 (8th Cir.1998) (holding that expert testimony regarding a report prepared by a third party was properly allowed); Gussack Realty Co. v. Xerox Corp., 224 F.3d 85, 94, 95 (2d Cir.2000) (finding that testimony was properly admitted from an expert who did not conduct

that " [t]he data available after nine months establishes that the EDTA-washed resin in Tris's proposed ANDA product reduces the rate of degradation by 57.3% over nine months and meets this part of the claim limitation. Following normal linear degradation, a similar reduction in degradation would occur after twelve months." Opening Report ¶ 67. As evidenced by Dr. Byrn's terse and conclusory statement, Dr. Byrn does not provide any explanation or "factual predicate" concerning the third party testing. See, e.g., Novartis, 271 F.3d at 1051. Indeed, nothing in Dr. Byrn's opinion suggests, let alone establishes, that the third party testing was scientifically acceptable, that Aptuit was qualified to perform the testing or that the product manufactured and tested by Aptuit was the same as Tris's ANDA product. Moreover, Dr. Byrn's opinion appears to be based, entirely, on information he was told by counsel and not based on first hand review or knowledge. See supra n. 3. Indeed, not only did Dr. Byrn not supervise, design or conduct the experiments about which he opined, but at the time of his Opening Report, Dr. Byrn had not independently reviewed any of the third party data and was, instead, relying solely upon information he was told by Plaintiffs' counsel. See id. Thus, unlike Dow Chemical, there is no evidence whatsoever to support Dr. Byrn's Opinion regarding the third party laboratory results. Because Plaintiffs have not set forth any basis for Dr. Byrn's opinion concerning the third party testing, let alone demonstrated that the product manufactured and

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his own tests)." That said, an expert's "unsupported conclusion on the ultimate issue of infringement is insufficient to raise a genuine issue of material fact." Arthur A. Collins v. Northern Telecom Ltd., 216 F.3d 1042, 1046 (Fed.Cir.2000). Instead the expert must include the facts upon which his conclusions were reached. See id.; Zelinski v. Brunswick Corp., 185 F.3d 1311, 1317 (Fed.Cir.1999). Here, Dr. Byrn did not independently evaluate the third party testing, nor the samples created by Aptuit, and thus, could not comment upon the reliability of the testing and whether it definitely supports his conclusions.

tested by Aptuit was the same as Tris's accused product, the Court finds that Dr. Byrn is unable to opine regarding the manufacture and testing of the third party data. Since there is no independent basis for relying on the third party test results, the record is devoid of any reliable analysis of those results; thus, the Court finds that the third party data is insufficient to defeat Defendants' motion for summary judgment.

B. Plaintiffs' Comparison of the Accused Tris product to Delsym

Next, Plaintiffs attempt to prove that Tris's ANDA product infringes the '882 patent by comparing the accused product to Delsym. In this motion, Defendants argue that because Plaintiffs have only compared Tris to Delsym, and have not compared Tris's product with EDTA to an identical pharmaceutical product without EDTA as required by Claim 23, Plaintiffs have failed to demonstrate infringement.

As discussed above, Claim 23 requires a comparison of "a drug-resin complex comprising adding a chelating agent" to "an otherwise identical pharmaceutical composition without the chelating agent." Thus, Claim 23 expressly requires a comparison between the accused product (with EDTA) and an "identical" pharmaceutical composition without EDTA. In that regard, Defendants initially argue that although Dr. Byrn compares Delsym to Tris's ANDA product, Plaintiffs have not demonstrated that Delsym is an identical pharmaceutical product for purposes of Claim 23.[6] In support of this argument, Defendants note that Dr. Byrn has not opined that Tris's product and Delsym are identical as required by Claim 23. Indeed, Defendants point to a chart contained in Dr. Byrn's Opening Report demonstrating that the Delsym and Tris products

[6]In addition, the Court notes that as discussed infra, because Delsym and Tris's ANDA product both contain EDTA, Plaintiffs have not met the requirements of Claim 23.

are, in fact, different. Further, Defendants argue that Plaintiffs' reliance on the alleged bioequivalence of Delsym and Tris is inapposite. For the reasons set forth below, the Court agrees.

Initially, the Court notes that nothing in the record demonstrates that Delsym and Tris are identical pharmaceutical products for purposes of Claim 23. Indeed, nowhere does Dr. Byrn opine that Delsym and Tris are identical products for purposes of the asserted claims. Moreover, a chart contained in Dr. Byrn's Opening Report expressly demonstrates that eight of seventeen ingredients in the Delsym and Tris products are different. Opening Report ¶ 64. At best, Dr. Byrn states that "Tris's proposed ANDA product's formulation show[s][sic] remarkable similarity to Delsym." Opening Report ¶ 64. However, the plain language of Claim 23 requires that the products be identical and not "remarkably similar" for purposes of demonstrating that the accused product infringes.

Moreover, to the extent that Plaintiffs rely on the bioequivalence of Delsym and Tris in order to satisfy the "identical" requirement of Claim 23, the Court finds that such reliance is misplaced. Indeed, as the Federal Circuit has explained:

> Bioequivalency and equivalent infringement are different inquiries. Bioequivalency is a regulatory and medical concern aimed at establishing that two compounds are effectively the same for pharmaceutical purposes. In contrast, equivalency for purposes of patent infringement requires an element-by-element comparison of the patent claim and the accused product, requiring not only equivalent function but also equivalent way and result. Different attributes of a given product may thus be relevant to bioequivalency but not equivalent infringement, and vice versa. As the Northern District of Illinois observed in the Sandoz case, "[i]f bioequivalency meant per se infringement, no alternative to a patented medicine could ever be offered to the public during the life of a patent." Sandoz PI Order, 486 F.Supp.2d at 776. Thus, while potentially relevant, the bioequivalency of an accused product with a product produced from the patent at issue is not sufficient to establish infringement by equivalents.

Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1298 (Fed. Cir. 2009).

Applied here, although Plaintiffs argue that Delsym and Tris's ANDA product are similar and, moreover, that the bioequivalence data demonstrates "the similarity between an innovator product and an accused product," nothing in the record demonstrates that Delsym and Tris's ANDA product are identical as required for the comparison in Claim 23. For these reasons, the Court finds that Plaintiffs have failed to establish that Delsym and Tris's ANDA product are identical for purposes of the asserted claims.

However, even assuming that this Court were to find that Delsym and Tris's ANDA product are identical for purposes of Claim 23, the Court finds that the record is barren of a comparison between the accused product (with EDTA) and an identical product without EDTA. Importantly, in their opening brief, Defendants argue that "[t]he purported similarity in stability between Tris Pharma's product and Delsym asserted by Dr. Byrn is also inapt because both products use EDTA. This says nothing about the relative stability of the Tris Pharma product when compared to an otherwise identical product made without EDTA, which is the comparison required by the patent claims." Defs' Br. at 5 (emphasis in original). Indeed, Plaintiffs have not disputed Defendants' assertion. In fact, Plaintiffs' Opposition Brief appears to focus solely on a comparison of Tris (with EDTA) to Delsym (with EDTA), Pls' Opp. 11-14, and Plaintiffs do not dispute Defendants' contention that the record does not demonstrate a comparison of Tris's ANDA product (with EDTA) to an identical pharmaceutical product without EDTA.

Moreover, in their responsive fact statement, Plaintiffs state that "Dr. Byrn considers the comparison of Tris Pharma's ANDA product (which uses EDTA) to Delsym with EDTA in

conjunction with, among other evidence, twelve month stability data conducted by Aptuit, a third party laboratory, that demonstrates that Tris Pharma's ANDA product has a more than 20% reduction . . .to an otherwise identical pharmaceutical composition without EDTA." Pls' Resp. Fact Statement ("Pls' Resp. FS") ¶ 1 (emphasis added). Initially, the Court notes that the responsive fact statement is internally inconsistent; Dr. Byrn's comparison of Tris's ANDA product to Delsym – two products with EDTA – is an entirely separate inquiry, and based on entirely separate data, than Dr. Byrn's opinion regarding the third party data. Thus, Plaintiffs' attempt to conflate the two is not helpful to this Court nor is it helpful to the analysis required under Claim 23. Moreover, based on the above statement the Court finds that Plaintiffs have expressly averred that Dr. Byrn compared two pharmaceutical products with EDTA, as opposed to two pharmaceutical products one of which contains EDTA and one which does not. Indeed, to the extent that Plaintiffs argue that Dr. Byrn considered the two drugs with EDTA "in conjunction" with the twelve month stability data, the Court notes that the Supplemental Report containing an analysis of the third party data has been struck from the record. Moreover, to the extent that Plaintiffs suggest that Dr. Byrn could rely on nine-months of stability testing conducted by Aptuit, I have already ruled that the record contains no factual predicate to support a proper consideration of this testing. Thus, at this point, there is nothing in the record to demonstrate that Plaintiffs compared Tris's ANDA product with EDTA to an identical product without EDTA as required by Claim 23. Thus, Plaintiffs cannot rely on this evidence to defeat Defendants' motion for summary judgment.

C. Experimental Tris product

Finally, Plaintiffs attempt to demonstrate infringement of the '882 patent by relying on

internal Tris data regarding an experimental Tris ANDA product made with Purolite C100MR resin. In this motion, Defendants argue that because Plaintiffs compared an experimental Tris product manufactured with a different resin than that utilized in the manufacture of the ANDA product, Plaintiffs have not demonstrated infringement. In addition, Defendants argue that because the experimental data upon which Plaintiffs rely encompasses only three months of testing (as opposed to the 12 months recited by Claim 23), such data fails to meet the requirements of the asserted claims. In response, Plaintiffs argue that although the experimental Tris product and the accused product are different, the addition of EDTA will have the same effect in both products. In addition, Plaintiffs argue that Dr. Byrn properly opined by extrapolating the three month data out to twelve months.

It is well-established that "[l]iteral infringement requires the patentee to prove that the accused device contains each limitation of the asserted claim(s). . . . If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." Bayer AG v. Elan Pharmaceutical Research Corp., 212 F.3d 1241, 1248 (Fed. Cir. 2000). Thus, it is beyond question that in order to demonstrate infringement, Plaintiffs bear the burden of showing that the accused Tris ANDA product meets the asserted claims of the '882 patent.

Here, in an attempt to show that Defendants infringed the '882 patent, Plaintiffs rely on internal Tris data regarding an experimental Tris ANDA product made with Purolite C100MR resin that shows a more than 20 percent reduction in rate of degradation over three months compared to the same formulation without EDTA. Opening Report ¶ 68; Byrn Decl., Ex. D., 10. Importantly, however, unlike the experimental Tris product, Tris's ANDA product does not contain C100MR, but instead, uses Amberlite IRP69, a different resin. Thus, there is no

evidence in the record showing that the accused product meets the asserted claims of the '882 patent.

In addition, the Court notes that the asserted claims require a comparison over twelve months to determine whether the addition of EDTA results in a 20 percent reduction in degradation. However, the data upon which Plaintiffs rely to demonstrate infringement comprise just three months worth of testing. In his Opening Report, Dr. Byrn opines that "[a]ssuming a normal linear degradation rate," the three month data "suggests that over twelve months the formulation with the EDTA-washed resin would continue to show decreased degradation compared with the formulation without EDTA-washed resin, supporting. . .this part of the claim." Opening Report ¶ 68. Thus, at best, Dr. Byrn has opined that an experimental Tris product that uses a different resin than that used in the accused product would show the requisite degradation if the three month data were extrapolated over a 12 months period. This, however, is not sufficient to meet Plaintiffs' burden of establishing that the accused Tris product shows a more than 20 percent degradation over a twelve month period as required by the asserted claims. For these reasons, Plaintiffs cannot rely on the evidence concerning Tris's experimental product to defeat the instant motion for summary judgment.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion for Summary Judgment is GRANTED.

Dated: December 20, 2011

/s/ Freda L. Wolfson
Freda L. Wolfson, U.S.D.J.